EXHIBIT G

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 1629
THIS DOCUMENT RELATES TO:	Master File No. 04-10981
ALL PRODUCT LIABILITY CASES	Hon. Patti B. Saris Magistrate Leo T. Sorokin

DECLARATION OF KEITH ALTMAN

I, Keith Altman declare and state as follows:

1. My name is Keith Altman. I am employed by the law firm of Finkelstein and Partners and serve as the Director of Adverse Event Analysis for the firm. My address and contact information is as follows:

   Keith Altman
   Director of Adverse Event Analysis
   Finkelstein & Partners
   436 Robinson Avenue
   Newburgh, NY 12550
   800-634-1212 x 9263
   kaltman@lawampmmt.com

2. A true and correct copy of my c.v. is attached as exhibit Altman-A.

3. I have been working with computers and computer data since age 13. At 13, I spent one year working with teacher Herbert Cohen on numerical simulations. I attended the State University of New York at Stony Brook as an undergraduate with a double major in Physics and Astronomy. While there, I held several paid and unpaid positions concerning software development and data analysis. For example, I was a paid employee of the Research Foundation of the State University of New York. In that capacity, I developed the data analysis software as well as control software for a particle accelerator in a quantum electronics lab. I also worked on computations associated with Supernova 1987A, infrared telemetry data, and developed a data model for the error analysis calculation associated with the distance to the Hyades Cluster. These and other similar projects contributed to my preparation to work with data and computers and I employ these skills and practices to this day.

4. As a fundamental part of my education, computers and data played an integral role. Aside from my research activities, I used computers extensively throughout my education.

5. In my professional capacity, I have been analyzing computer data for the last 19 years. I have been responsible for the preparation and computational support of thousands of data sets in that time. I am routinely engaged to perform computations on these data sets to support individuals in a wide variety of disciplines. Regardless of the content of the data, the principles associated with data computations are generally invariant and, therefore, I am able to work with computer data in areas I have never worked on before.

6. I have been working with pharmaceutical adverse event data since 1998. Adverse event data is data associated with untoward effects of pharmaceutical products. I have possession of the entire publicly-available adverse event data from the FDA dating from 1969. To date, that represents more than three million adverse event reports. I have prepared those data into a database from which I routinely provide customized data compilations.

7. In my professional capacity I have provided assistance to the FDA with respect to its handling of data. For example, in mid 2003 I detected a flaw in the data provided by the FDA as part of its adverse event reporting extracts made available to the general public. This flaw, involving erroneous calculations of last best cases for reports by the FDA, would likely have led to serious errors in working with the data. I communicated my discovery to Paul Reinstein of the FDA, the individual responsible for the extract of the FDA AERS data. As a result of my discovery the FDA has abandoned the practice that affected the data and communicated this decision publicly to all users of the AERS data worldwide.

8. I have compiled analyses of adverse event data with the use of math and computers for approximately 50 different pharmaceutical products, including Diet Drugs, Lariam, Accutane, Meridia, Rezulin, Effexor, Paxil, Baycol, Hormone Therapy, Children's Advil, Viagra, Ortho Evra, and Neurontin. These analyses include studies of adverse events from each type of clinical study, including blind studies, double blind placebo studies, and uncontrolled studies in which the effect of a drug on a human is compared to the effect of the same drug within a larger group of humans. These analyses also include studies of clinical reports to the FDA submitted by a pharmaceutical company seeking approval for a new drug, known as a new drug application, and studies of such reports after a drug has received FDA approval. These analyses also include studies of individual case reports and adverse event reports which are required by law to be maintained by the FDA and by the pharmaceutical company whose drug or product is the subject of such reports.

9. The type of mathematical computations I perform as a part of my routine practice include counts of numbers of reports for various adverse event terms, calculations of percentages between drugs, comparisons of such percentages (Proportional Reporting Rate or PRR), and time trends of reporting.

10. I routinely do this type work outside of litigation and, in particular, in support of drug development projects which lead to application to the FDA for new drug approval on

behalf of pharmaceutical companies and on behalf of the experts who evaluate such drugs for the purpose of NDA submissions and label submissions to the FDA. Included in my non-litigation work I have performed the statutorily-mandated safety analysis for three new drug applications, two of which have been approved and the third of which is in the final stages of approval. Of the two approved I performed the safety analysis for one and performed the post marketing adverse event section, including the analysis, for the other. The FDA specifically reviewed my data computations in all these submissions and found no errors, nor did the FDA express any concerns of either my methods or the accuracy of the data I submitted.

11. I used the same methodology in preparing data for use by the experts in this case that I use in my drug development projects.

12. I am a member of the International Society of Pharmacoepidemiology and the Drug Information Association. In addition, I regularly review abstracts for the International Society of Pharmacoepidemiology (ISPE) annual scientific meeting. In 2007, I submitted three abstract proposals to the ISPE scientific committee regarding the work I do with the FDA adverse event data, specifically including my work on Proportional Reporting Rate analysis. All three abstracts were peer reviewed and were accepted for presentation at the conference. One of the abstracts was selected for one of only twelve oral presentations at the methods portion of the conference hosted by Ken Rothman, one of the preeminent epidemiologists in the world.

13. I am not assisting in this litigation in an expert witness capacity. However, I have been qualified as an expert witness in my field by a court on the topics of adverse event reporting, adverse event reporting systems, and pharmacovigilance. South Carolina v. Pittman (2005).

14. In addition, the work I do to provide summaries of clinical data, adverse event reports, and pharmacovigilance practices to testifying expert witnesses has been accepted as work on which expert witnesses in specific litigation may rely under Federal Rule of Evidence Rule 703. Furthermore, these charts are objective summaries of voluminous sets of data. All of my work is readily verifiable and I routinely provide all of the underlying data for review.

15. In addition to the publicly available adverse event data from the FDA, I am in possession of all of Pfizer's discovery in this case. I have spent extensive time working with Pfizer's internal adverse event database. I have employed the same methods to analyze Pfizer's database as with other adverse event databases and other databases in general and am confident that I am qualified to accurately report the contents of the database.

16. Neither Pfizer, Inc., in the motions and briefs filed herein, nor any witness in this case have stated that any computations performed by me in this case was incorrect in any way. No math error, nor any statistical error, nor any error in allocating the nature, type, frequency, or degree of any evidence of suicides or attempted suicides by any patient

taking Neurontin has been stated or even claimed by Pfizer or any witness in this case to have been found in my work.

17. All charts, tables of data, and allocations of patient type, (such as psychiatric, pain, and 'other' patients and the years, numbers, and frequency of suicide reports, suicide attempt reports, and reports of behavior associated with suicidality) were of the type which I routinely provide to the FDA and to expert witnesses who need such data and charts. I have not exercised any subjective judgment concerning the data. I checked them for accuracy before I provided them to Pfizer and to Dr. Blume and have checked them since. I found no errors in them.

18. The work I provided to Dr. Blume is of the type she routinely uses both in her practice in submitting new drug applications to the FDA and as an expert witness.

19. Prior to the deposition of plaintiffs' experts in this case, I personally prepared and submitted a computer data disk with all of the computational materials I had used and prepared for this litigation for adverse event compilations and objective summaries. The original source of the data was Pfizer's own records and the publicly available FDA data. I provided a copy of this data disk to the defendants in this case.

20. I was involved with a meet and confer with defense counsel to discuss the contents of the disk. Defense counsel had the opportunity to question me about the contents of the disk to their satisfaction. Using the disk I had provided to them, Pfizer and its counsel had the ability to verify the accuracy of any chart prepared for or by Dr. Blume if they chose to do so.

21. In early 2004, as part of the routine analysis of FDA adverse event data, the data showed a large increase in the number of completed suicide reports among Neurontin patients reported by Pfizer in the first half of 2003. Specifically, the data showed that between November 1997 through the end of 2002, Pfizer reported 8 completed suicide reports to the FDA. This yields 1.6 reports per year. The data also showed that in the *first* half of 2003, the company reported 17 reports of completed suicide to the FDA. This yields 34 reports per year and represents a 20 fold increase in the reporting rate of suicide.

22. These observations were the basis for my filing a citizen's petition with the FDA seeking to change the label and include a warning for completed suicide which was not in the label at that point in time. In this case, Pfizer has suggested that the source of the data in my citizen's petition was in some way influenced by notoriety associated with advertising performed by my firm, Finkelstein & Partners. This is not true.

23. Pfizer and its witness Dr. Weiss-Smith have misrepresented or misinterpreted the timing of these increases. Contrary to the representations by Defendants, these increases in Neurontin suicide reports were not as a result of publicity from the citizen's petition or from any advertising effort by Finkelstein & Partners. The source of the seventeen reports of completed suicide reported by Pfizer to the FDA, which took place in the first half of 2003, were poison control centers, not clients or potential clients who wanted to

sue Pfizer. Importantly, I did not join Finkelstein & Partners until the second half of 2003 and neither Finkelstein and Partners nor I began to review the subject of Neurontin litigation until after I joined the firm.

24. With respect to any notoriety bias, Dr. Blume has always requested that I confine analyses to data before the 3rd quarter of 2003 for signal detection purposes. She clearly recognized that such a bias was possible after that point in time and wanted to be sure that her opinions were not influenced by such data. On occasion, she would ask me to go beyond that point in time for the purpose of seeing the effect of the notoriety bias.

25. The following statements address mistakes, misrepresentations, or misleading statements made by Pfizer in the pending motions to exclude plaintiffs expert witnesses (hereafter the 'Daubert motion') or for summary judgment.

26. On page 39 of the Daubert motion brief the Defendants mis-state my involvement in the *Meridia* litigation. Contrary to their statements, I was not an expert witness in that case, and I had never been offered or disclosed as an expert witness in that case. Further, in the *Meridia* opinion cited by Defendants, the judge ruled that I had not been disclosed as an expert nor did I need to be an expert witness statistician to provide the basic computational analysis in that case. Defendants also state that the judge excluded my opinions in the *Meridia* case. That is not true; the opinions excluded were not mine and I do not agree with the expert's misuse of charts I created for the purposes of stand alone proof of causation.

27. Additionally, Defendants here claim that the *Meridia* Court ruled that Proportional Reporting Rate (PRR) analysis is unreliable for all purposes (Defendants' Daubert Motion at 40). The *Meridia* court ruled only that *standing alone*, PRR is insufficient to "speak directly to the issue of causation." Here, in the Neurontin litigation, I did not calculate PRR's for Dr. Blume to stand alone to establish that Neurontin is the cause of suicide or of attempted suicide nor, to my knowledge, has Dr. Blume expressed that opinion. Her opinion is and, to my personal knowledge has been, that the method for which a PRR is used is to evaluate whether there is *a signal of a safety problem* that, when combined with other information, supports the conclusion that Neurontin has the biological capacity to cause patients who take it to commit or attempt suicide.

28. Pfizer counsel also claim, Daubert motion page 41, that a chart I created demonstrates the absence of causation. This statement demonstrates that they do not understand the chart. Attached as Exhibit Altman-B is a copy of the chart.
    a. Defendants claim that the chart demonstrates that the reporting rate of suicide went down after the first quarter of 1994 which demonstrates a lack of a causal relationship.
    b. Warner – Lambert (Pfizer's predecessor in marketing Neurontin), received the first completed suicide report from post marketing in the fourth quarter of 1994.
    c. Before this time the cumulative percentage of suicide reports was 0; it is not normal methodology when graphing such data to graph a time period before there was an event.

d. After the first event, there were no suicides until 1997. Since the total number of reports was increasing during the same time period, the percentage *would* go down. The defendants use such data to claim that the chart shows there is no causal relationship.
e. However, this disregards that there were relatively few serious adverse event reports received by the company in the first few years of marketing. Therefore, isolated reports can have a large effect on the percentages. Such effects are routinely disregarded.

29. Pfizer, in its criticism of the chart, disregards that by the 4th quarter of 2002, covering the years when the off-label use of Neurontin is at its peaks, the percentage of serious adverse events had exploded.

30. Pfizer misrepresented to the court that this is because of notoriety bias from the public awareness of the citizens petition to the FDA or from the efforts of Finkelstein & Partners to bring the suicidality potential of Neurontin to the public's attention, but that is not true since the statistical increase came long before any involvement by Finkelstein and Partners (3rd Quarter 2003), and long before the observations I made led me to file the citizen's petition.

31. More importantly, and, mathematically, for the percentage to increase so much after the drug had been on the market for as long as it had means that the percentage of reports for the first half of 2003 were enormously different. After the completion of discovery in this case, it is now observed that in fact, there were approximately 782 serious adverse event reports in the period October 1, 2002 to June 30, 2003, including 22 completed suicides (some 3% of the serious adverse event reports in that period).

32. I attach several additional charts prepared by me at the direction of Dr. Blume. These charts are based upon the data I provided to defendants and which I extracted from the adverse event data provided by the defendants and the FDA database, themselves too voluminous and extensive to provide in their entirety. I prepared these charts using the same methodology as the work I do for new drug applications and for safety summaries as well as for work to be relied on by expert witnesses.

33. These charts are consistent with Dr. Blume's opinions expressed in her report and in her deposition. They represent objective numerical summaries of the contents of the databases. Dr. Blume may use them as demonstrative exhibits in the hearing or in any trial of this case.

34. To the best of my knowledge, no Pfizer employee nor any expert ever testified that the company had performed any computations or summaries concerning adverse events in off label populations for any off-label indication other than neuropatic pain.

35. The defendant companies have maintained that there was no signal for suicidal behavior at any time before the 3rd quarter of 2003.

36. However, within the company database of adverse events is data that identifies the indication (the medical condition of the patient) for which the drug was used. Under the direction of Dr. Blume, I prepared a chart that showed the percentage of suicidal and self injurious behavior reports against serious adverse event reports for various groups of Neurontin indications. This chart is attached as exhibit Altman-C to this affidavit. The chart demonstrates that there appears to be a large difference between psychiatric indications and other indications. According to standard statistical calculations, the results are statistically significant by 6/30/99.

37. I attended the defense expert deposition of Dr. Sheila Weiss-Smith in January of 2008. As part of her expert report on page 21, Dr. Smith-Weiss provided a chart suggesting that there was no signal for either suicide or suicide attempt until after 2004. Exhibit Altman-D. Her use of the chart was in error.
    a. Before November of 1997 there was no term in the FDA database for completed suicide. Any chart that contained a time period before 1997 would not contain any suicide for any drug or the background.
    b. If the number of reports of an event is 0, then the percentage of reports for that event is also 0.
    c. Dr. Weiss-Smith stated that she calculated the ratio as one percentage divided by the other. If the two percentages are 0, then one would divide 0/0. It is a mathematical fact that division by 0 is undefined. Therefore, 0/0 is undefined.
    d. Since 0/0 is undefined, any chart that shows such a ratio as any value other than undefined is factually wrong.
    e. Dr. Weiss-Smith's chart shows the ratio for suicide prior to 1998 as 0. Since the ratio is 0/0, her chart is factually wrong.
    f. The only mathematical interpretation of her chart is that prior to 1998 there were zero suicides in Neurontin while there was at least 1 suicide in the background of all other drugs. This is mathmatically impossible as shown above.
    g. Starting the completed suicide data in 1994 has the mathematical effect of causing differences to become visible later in time than they really occur. As an example, if there were 100 total reports for Neurontin before suicide was used as a term and then in the first year of use there were 10 suicide reports out of 20 total reports, by starting in 1994, the percentage is 10/120 or 16.7% against 10/20 or 50%.

38. At the direction of Doctor Blume, I created a correct version of the chart that Dr. Weiss-Smith attempted to create but used the following corrections.
    a. First, since the term for completed suicide did not even exist in the MedDRA lexicon before November 1997, the chart begins in the 4th quarter of 1997.
    b. Instead of using the single term 'completed suicide,' Dr. Blume instructed me to use the MedDRA term "suicidal and self injurious behavior;" that phrase includes completed suicide, suicide attempt, and suicidal ideation. This is a standard definition from the medical dictionary used by the FDA.
    c. Dr. Blume then instructed me to use serious reports only. There is a regulatory definition for serious events. Because some companies may request waivers to

not submit non-serious reports, it is standard methodology in calculating the statistics of adverse events and pharmacovigilance to exclude non-serious reports.

d. The reports were then limited to instances in which the reporter believed that there might be some relationship between the drug and the event.
e. Finally, as discussed above regarding the methodology used for composing PRR charts, the percentages of both the background and the drug were shown instead of the ratio.
f. For the time period in which there were no events, this corrects Dr. Weiss-Smith's chart in her report.

39. A review of the chart attached as exhibit Altman-D shows that there is a statistically significant difference between Neurontin and background starting in the 4th quarter of 1999. This result is consistent with the computational summary of the off-label indications discussed above.

40. At Dr. Blume's request, I reviewed the chart prepared by Pfizer employee Christopher Pacella attached as exhibit Altman-E. I was asked to prepare the information in a similar manner based upon the Pfizer internal database which was available to me. Furthermore, Dr. Blume asked that I limit the computation to serious reports and run the data using MedDRA high level terms. Attached as exhibit Altman-F is the results of this anlaysis.

41. To the best of my knowledge, all charts and computations created by me in this litigation are true and accurate summaries of voluminous materials produced by Pfizer in this litigation or publicly available from the FDA. I have exercised no subjective interpretation of any of the data and if desired, Pfizer has the ability to verify everything I have done.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 3rd day of April, 2008, in Massapequa Park, NY.

Keith Altman

Altman April 3, 2008 Declaration

Exhibit Altman-A

Keith L. Altman

Finkelstein & Partners
436 Robinson Avenue
Newburgh, NY 12550
800-634-1212 x 9263
kaltman@lawampmmt.com

Specific Expertise - Knowledge Management

Works with attorneys to help them acquire data, turn that data into knowledge, and manage the knowledge. Often the data is in an electronic format which offers many discovery challenges.

Educational Experience

B.S. Program, Astronomy/Physics, 1985-1989, Magna cum Laude, State University of New York at Stony Brook
J.D. Concord Law School, 2008

Computer Experience

Languages: Basic, Fortran, Pascal, Assembly, C, APL, SQL Windows, Visual Basic
Databases: Microsoft Access, SQL

Research Experience

1981-1982, Corroboration with Teacher Herbert Cohen, Farmingdale Public Schools.
Worked on developing models for gaming systems using Fibonacci series. Developed various computer models to analyze gaming systems.

1985-1989, Laboratory of Professor Peter M. Koch, Quantum Electronics Group, Physics Department, State University of New York at Stony Brook.
Work as a paid employee of the Research Foundation of the State University of New York. Was responsible for developing computerized tools to analyze experimental data. Developed applications for instrument control and measurement. Used sophisticated computer modeling to design microwave klystrons for experiments.

1987, Professor Michael Simon, State University of New York at Stony Brook
Developed computer models to analyze infrared imaging data from various telescopic sources.

1988, Professor Gerry Brown, State University of New York at Stony Brook
Developed computer models to analyze theoretical data concerning Supernova 1987A.

1988, Professor Dean Peterson, State University of New York at Stony Brook

Analyzed observational data concerning brightness of stars in the Hyades cluster. Determined error in observational data helping to redefine the distance to the cluster which is used as a yardstick for many calculations of stellar distances.

Relevant Work Experience

1989-1995, Legal Systems Manager, Beta Business Products
1995-2003, President, The Fibonacci Systems Group; Vice President, The Fibonacci Group
2003-, Managing Director, Complex Litigation Division, Finkelstein & Partners
2003-, Director of Adverse Event Analysis, Finkelstein & Partners

Relevant Litigation Experience

Member of Working Group One (Electronic Discovery) for the Sedona Conference.

18 years experience working in the legal industry.

MindSet

Developed a suite of tools to assist attorneys in managing litigation related data and knowledge.

Breast Implant Litigation

Became involved in the litigation towards the very end (last two years). Some notable tasks.

- Medical Science Literature Database
- Assisted in preparation for trials for Baxter, 3M and Bristol Meyers-Squibb.

FenPhen Litigation (representative tasks similar to other litigation projects)

Serves as the chief plaintiff consultant throughout the United States for litigation in the state courts. Also assisted the MDL in a similar capacity. In this role is responsible for the following.

- Development of discovery demands
  Helps draft discovery demands to take records retention issues and electronic information into account. Also helps establish opposing party's information management strategy.
- Collection of production materials
  Serves as the repository for all discovery materials.
- Review of production materials
  Reviews materials to access completeness and reasonableness in respect to complying with formats described in discovery demands.
- Organization of production materials
  Takes the materials and prepares them for use by over 100 law firms. Converts them to a uniform format and catalogues the materials.
- Distribution of production materials for attorney review
  Sends materials out to various attorneys and works with them to provide tools so that materials may be reviewed efficiently.

- Collection of attorney work product
  Receives materials from attorneys and assembles them into a repository.
- Management of attorney work product
  Provides expertise in integrating attorney work product with source production materials.
- Preparation for depositions
  Works with the attorneys to help them integrate production materials into the depositions. Helps prepare exhibit lists.
- Deposition support
  Attends various depositions as both an expert and for support. Suggested questions during depositions of computer personnel.
- Trial preparation
  Works with the attorneys to prepare all trial materials for use. Helps develop visual aids and presentation strategy. Coordinates audio-visual needs for the court room.
- Trial Presentation
  Attends the trial to assist in presentation of exhibits.
- Medical Science Literature Database
  Developed the strategy for collecting and managing over 4,000 medical articles related to the litigation. Distributed this database to various law firms around the United States.

Major Patent Litigations

Coordinated document productions sent and received for various patent litigations. Helped prepare for trials in many of the same litigations.

Construction Litigation

Worked on trial preparation and presentation of several construction related cases. Most recently, provided trial support for GCNA v. City of Cleveland in federal court in Akron Ohio.

Video Teleconferencing Trial

In Turcinovic v. Floch (New Jersey), provided an affidavit which helped to convince the judge to allow the plaintiff, a quadriplegic residing in Chicago, to testify during his trial by video teleconferencing link. This was the first time in the United States that a plaintiff was allowed to testify in this way. Coordinated all technology at both sites. Although the case settled on the eve of trial, the settlement was accepted by the teleconferencing link with the attorneys conducting an interactive conversation with the plaintiff.

Document Archival Facility Fire

Working for defendant sprinkler manufacturer in a case involving documents destroyed in a fire at a document archive facility. Established an information management infrastructure to coordinate several hundred thousand pages of discovery materials. Providing assistance in assessing compliance with records retention policies on the part of plaintiffs.

Other Litigation Projects

MTBE
Cooper Tire
Lotronex
PPA
Baycol
Accutane
Oxycontin
Vioxx
Celebrex
Lariam
Enbrel
Remicade
Neurontin
Ortho-Evra
SSRI's

Adverse Event Analysis Experience

Developed a collection of tools for the analysis of FDA adverse event data. These analyses are commercially available to the general public.

Provided ADE analysis for 120-Day safety updates of major pharmaceuticals.

Interacts with the FDA on adverse event reporting issues concerning the AERS database.

Developed adverse event section for recently submitted new drug application.

Speaking Experience

Has spoken at several Mealeys conferences as well as numerous bar associations on topics of electronic discovery and litigation technology.

Was on the faculty of the Judicial College for the state of New Jersey in November, 2001.

In June, 2002, spoke at a symposium on electronic discover sponsored by the Federal Bar Association. The proceedings of this symposium are scheduled to be released in book form late 2002.

In July, 2002, spoke on preservation of electronic information at the annual meeting of the Association of Trial Lawyers of America.

In July 2003, spoke on electronic discovery at the annual meeting of the Association of Trial Lawyers of America.

Was on the faculty for the Judicial College for the state of Mississippi in October 2003.

Course advisor and speaker for ATLA seminar on electronic discovery January 2004

In July 2004, spoke on electronic discovery at the annual meeting of the Association of Trial Lawyers of America. CLE credit was awarded for this talk.

In July 2005, spoke on electronic discovery at the annual meeting of the Association of Trial Lawyers of America. CLE credit was awarded for this talk.

In July 2006, spoke on electronic discovery at the annual meeting of the Association of Trials Lawyers of America. CLE credit was awarded for this talk.

In July 2007, spoke on electronic discovery at the annual meeting of the Association of Trials Lawyers of America. CLE credit was awarded for this talk.

In August 2008, Oral Presentation on Methods at the annual meeting of the International Society of Pharmacoepidemiology in Quebec City. Also presented two posters at poster session. Selection for oral presentation and posters was by peer review.

Expert Testimony

South Carolina v Pittman. Admitted as expert on adverse event reporting analysis and adverse event reporting systems. February, 2005

Publishing Experience

Book Chapter on electronic discovery in Electronic Information: Its Life Cycle edited by Alan Blakely published by the Federal Bar Association.

Deciphering the Adverse Event Reporting System. Bert Black and Keith Altman. Trial Magazine, March 2005.

Make the Most of e-Data Experts. Keith Altman. Trial Magazine, October 2005.

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Exhibit Altman-B

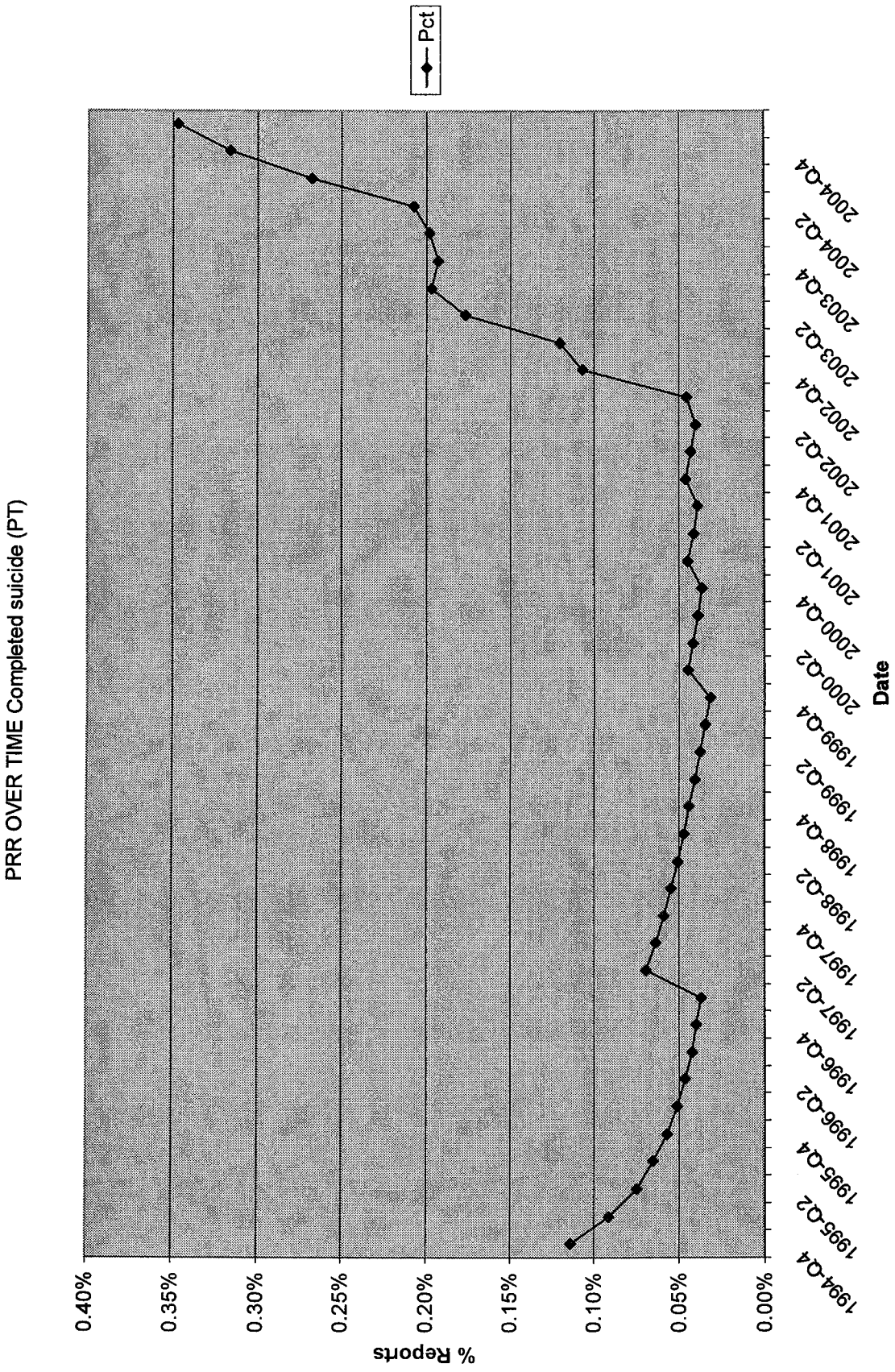

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Exhibit Altman-C

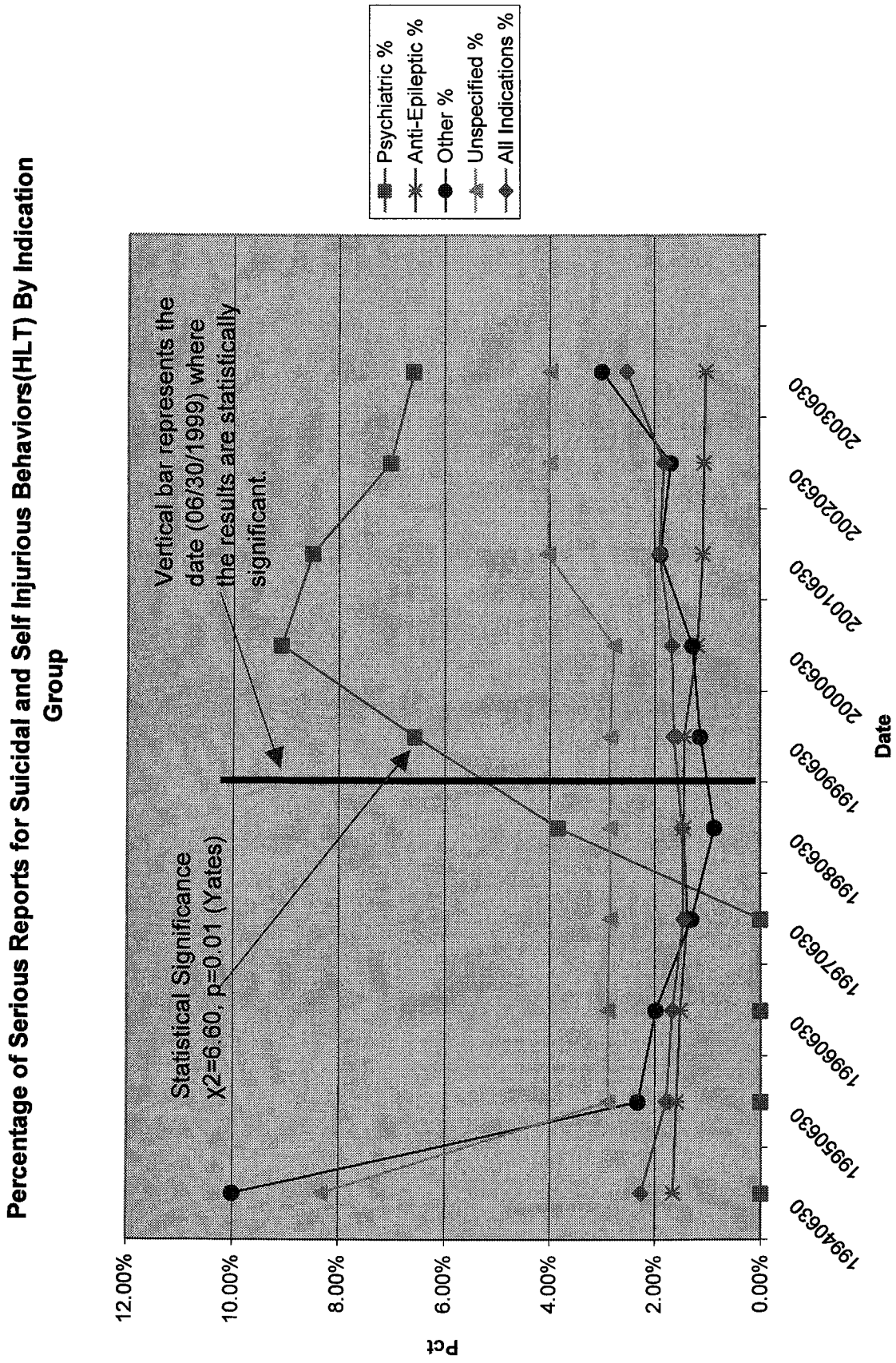
Percentage of Serious Reports for Suicidal and Self Injurious Behaviors(HLT) By Indication Group
Psychiatric %
Anti-Epileptic %
Other %
Unspecified %
All Indications %
Vertical bar represents the date (06/30/1999) where the results are statistically significant.
Statistical Significance
X2=6.60, p=0.01 (Yates)
12.00%
10.00%
8.00%
6.00%
4.00%
2.00%
0.00%
Pct
19940630
19950630
19960630
19970630
19980630
19990630
20000630
20010630
20020630
20030630
Date

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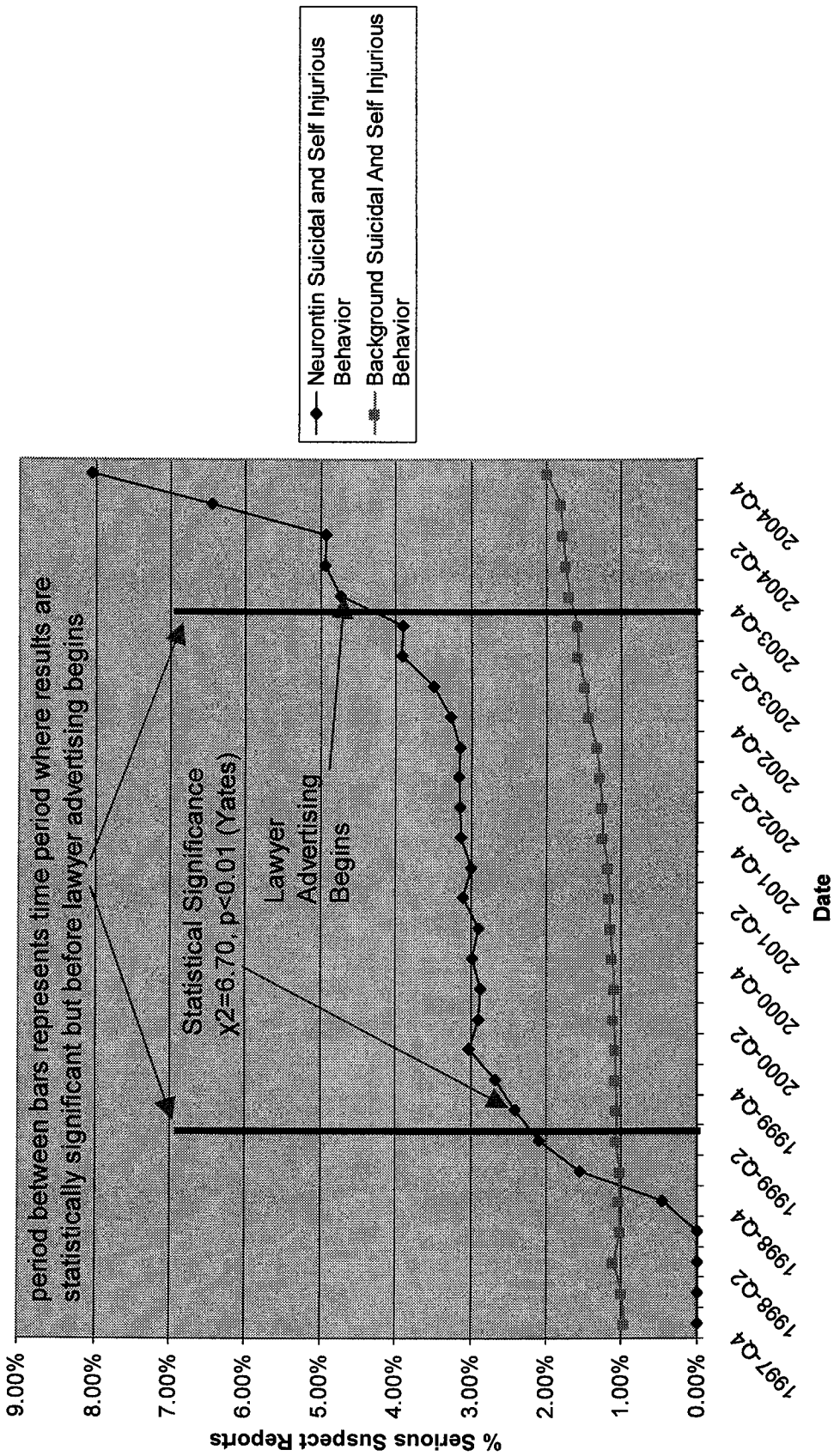
Exhibit Altman-D

Cumulative Percentage Reports of Suicidal and Self Injurious Behavior(HLT) for Neurontin vs. Background of All Other Drugs



Altman April 3, 2008 Declaration

Exhibit Altman-E

From: Pacella, Christopher
Sent: Friday, July 12, 2002 2:36 PM
To: Arena, Philip; Cortina, Lisa; Glanzman, Robert; Hassell, Alan; Hauben, Manfred; Patel, Manini; Quintana, Alvaro; Zhang, Tina
Subject: RE: gabapentin Core Working Group Meeting scheduled for July 25, 2002

To All,

Please find attached a summary of the post-marketing reports for gabapentin through 31Mar02. I have high-lighted all of the adverse events that are approximately 1% or equal to or greater than 1%. In addition, I have indicated whether it is labeled or unlabeled in the current IPI and USPI and have recommended whether the event should be reviewed or not. Please review this list prior to our meeting on 25Jul02, as this will expedite our meeting time. Please bring all comments to the meeting.

Gaba
945_arisg_wears_al

If there are any questions prior to our meeting, please do not hesitate to contact me.

Thank you.
Best regards,
Chris

Tracking:

Recipient	Delivery	Read
Arena, Philip	Delivered: 7/12/2002 2:36 PM	Read: 7/12/2002 4:40 PM
Cortina, Lisa	Delivered: 7/12/2002 2:36 PM	Read: 7/15/2002 6:23 PM
Glanzman, Robert	Delivered: 7/12/2002 2:36 PM	Read: 7/12/2002 3:31 PM
Hassell, Alan	Delivered: 7/12/2002 2:36 PM	Read: 7/12/2002 2:41 PM
Hauben, Manfred	Delivered: 7/12/2002 2:36 PM	Read: 7/15/2002 4:02 PM
Patel, Manini	Delivered: 7/12/2002 2:36 PM	Read: 7/12/2002 2:50 PM
Quintana, Alvaro	Delivered: 7/12/2002 2:36 PM	Read: 7/12/2002 2:37 PM
Zhang, Tina	Delivered: 7/12/2002 2:36 PM	Read: 7/12/2002 2:36 PM

	A	B	C	D	E	F	G
1							
2	**Summary of Spontaneous Post-Marketing Reports for Gabapentin, as of March 31, 2002**						
3	**All Cases**						
4	***BODY SYSTEM /***		**Number of Events**	**Percentage (Events/Cases)**	(L = Labeled) (NL = Not Labeled)		
5	**PREFERRED TERM**				**IPI**	**USPI**	**Review**
6	***BODY AS WHOLE***						
7	ABDOMEN ENLARGED		20	0.18			
8	ABDOMINAL PAIN		190	1.72	L	L	No
9	ABSCESS		10	0.09			
10	ACCIDENTAL INJURY		212	1.92	L	NL	No
11	ACCIDENTAL OVERDOSE		27	0.25			
12	ADENOMA		1	0.01			
13	ADMINISTRATION ERRONEOUS		1	0.01			
14	AGGRAVATION REACTION		11	0.1			
15	AIDS		3	0.03			
16	ALLERGIC REACTION		73	0.66	NL	NL	Yes
17	ALTERED DRUG LEVEL		43	0.39			
18	ALTERED HORMONE LEVEL		1	0.01			
19	ANAPHYLACTOID REACTION		10	0.09			
20	ANAPHYLAXIS		1	0.01			
21	APLASIA		1	0.01			
22	ASCITES		4	0.04			
23	ASTHENIA		584	5.3	L	L	No
24	BACK PAIN		126	1.14	L	L	No
25	BIRTH WEIGHT SUBNORMAL		5	0.05			
26	BODY ODOR		5	0.05			
27	CACHEXIA		3	0.03			
28	CARCINOMA		23	0.21			
29	CELLULITIS		15	0.14			
30	CHEST PAIN		92	0.83	NL	NL	Yes
31	CHEST PAIN SUBSTERNAL		1	0.01			
32	CHILLS		51	0.46			
33	CHILLS AND FEVER		3	0.03			
34	CHOLINERGIC SYNDROME		1	0.01			
35	CHROMOSOME ABNORMALITY		2	0.02			

	A	B	C	D	E	F	G
36	CLUBFOOT		1	0.01			
37	COLLAGEN DISORDER		3	0.03			
38	CONGENITAL ANOMALY		25	0.23			
39	CYST		16	0.15			
40	DEATH		141	1.28			No
41	DERMATOMYOSITIS		2	0.02			
42	DRUG INTERACTION		461	4.18			?
43	DRUG LEVEL DECREASED		43	0.39			
44	DRUG LEVEL INCREASED		73	0.66			
45	EDEMA FACE		7	0.06			
46	EDEMA GENERALIZED		1	0.01			
47	EXPOSURE IN UTERO		54	0.49			
48	FACE EDEMA		131	1.19	L	L	No
49	FETAL DISORDER		4	0.04			
50	FEVER		107	0.97	L	L	No
51	FEVER MALIGNANT		1	0.01			
52	FLU SYNDROME		49	0.44			
53	GANGRENE		3	0.03			
54	GENERALIZED EDEMA		63	0.57			
55	GRANULOMA		4	0.04			
56	HALITOSIS		2	0.02			
57	HANGOVER EFFECT		13	0.12			
58	HEADACHE		440	3.99	L	L	No
59	HEMOPERITONEUM		1	0.01			
60	HEMORRHAGE		1	0.01			
61	HEMOTHORAX		1	0.01			
62	HERNIA		9	0.08			
63	HORMONE LEVEL ALTERED		45	0.41			
64	HYDROCEPHALUS		1	0.01			
65	HYPERTROPHY		2	0.02			
66	HYPOTHERMIA		20	0.18			
67	IMMUNE SYSTEM DISORDER		7	0.06			
68	IMMUNOGLOBULINS INCREASED		3	0.03			
69	INCREASED DRUG EFFECT		1	0.01			
70	INFECTION		104	0.94	L	NL	No
71	INFECTION MASKED		1	0.01			

	A	B	C	D	E	F	G
72	INFECTION PARASITIC		1	0.01			
73	INFECTION SUPERIMPOSED		1	0.01			
74	INJECTION SITE REACTION		2	0.02			
75	INTENTIONAL INJURY		2	0.02			
76	INTENTIONAL OVERDOSE		189	1.72			No
77	LAB TEST ABNORMAL		103	0.93	NL	NL	Yes
78	LABORATORY TEST INTERFERENCE		1	0.01			
79	LACK OF DRUG EFFECT		193	1.75			No
80	LE SYNDROME		17	0.15			
81	MALAISE		141	1.28	L	L	No
82	MEDICATION ERROR		91	0.83			
83	MONILIASIS		7	0.06			
84	MUCOUS MEMBRANE DISORDER		5	0.05			
85	MULTIPLE CONGENITAL ANOMALIES		1	0.01			
86	NECK PAIN		17	0.15			
87	NECK RIGIDITY		6	0.05			
88	NEOPLASM		42	0.38			
89	NEUROLEPTIC MALIGNANT SYNDROME		2	0.02			
90	NEUROTRANSMITTER LEVEL ALTERED		2	0.02			
91	NO DRUG EFFECT		26	0.24			
92	OVERDOSE		288	2.61			No
93	OVERDOSE ACCIDENTAL		1	0.01			
94	OVERDOSE INTENTIONAL		7	0.06			
95	OVERDOSE/INTOXICATION		10	0.09			
96	PAIN		535	4.85	L	NL	No
97	PAIN ABDOMINAL		14	0.13			
98	PAIN BACK		5	0.05			
99	PAIN CHEST		6	0.05			
100	PAIN NECK		2	0.02			
101	PELVIC PAIN		10	0.09			
102	PERINATAL DISORDER		12	0.11			
103	PERITONITIS		2	0.02			
104	PHOTOSENSITIVITY REACTION		25	0.23			
105	REACTION AGGRAVATED		66	0.6			
106	REACTION UNEVALUABLE		347	3.15			No
107	SARCOIDOSIS		3	0.03			

	A	B	C	D	E	F	G
108	SARCOMA		1	0.01			
109	SEPSIS		25	0.23			
110	SERUM SICKNESS		1	0.01			
111	SHOCK		9	0.08			
112	SUDDEN DEATH		22	0.2			
113	SUICIDE ATTEMPT		26	0.24			
114	TOLERANCE DECREASED		3	0.03			
115	TOLERANCE INCREASED		6	0.05			
116	UNEXPECTED BENEFIT		25	0.23			
117	VIRAL INFECTION		2	0.02			
118	**Sub Total**		**5661**				
119							
120	***CARDIOVASCULAR SYSTEM***						
121	ANGINA PECTORIS		15	0.14			
122	AORTIC STENOSIS		1	0.01			
123	ARRHYTHMIA		26	0.24			
124	ARTERIOSCLEROSIS		3	0.03			
125	ARTERITIS		1	0.01			
126	ATRIAL ARRHYTHMIA		3	0.03			
127	ATRIAL FIBRILLATION		12	0.11			
128	ATRIAL FLUTTER		4	0.04			
129	ATRIAL SEPTAL DEFECT		1	0.01			
130	AV BLOCK		2	0.02			
131	AV BLOCK COMPLETE		1	0.01			
132	AV BLOCK FIRST DEGREE		1	0.01			
133	BIGEMINY		1	0.01			
134	BRADYCARDIA		33	0.3			
135	BUNDLE BRANCH BLOCK		4	0.04			
136	CARDIAC ARREST		3	0.03			
137	CARDIOMEGALY		6	0.05			
138	CARDIOMYOPATHY		3	0.03			
139	CARDIOVASCULAR DISORDER		40	0.36			
140	CEREBRAL HEMORRHAGE		6	0.05			
141	CEREBRAL INFARCT		4	0.04			
142	CEREBRAL ISCHEMIA		15	0.14			
143	CEREBRAL THROMBOSIS		1	0.01			

	A	B	C	D	E	F	G
144	CEREBROVASCULAR ACCIDENT		40	0.36			
145	CEREBROVASCULAR DISORDER		5	0.05			
146	CONGESTIVE HEART FAILURE		15	0.14			
147	CORONARY ARTERY DISORDER		4	0.04			
148	CORONARY OCCLUSION		1	0.01			
149	DEEP THROMBOPHLEBITIS		13	0.12			
150	ECG ABNORMAL		2	0.02			
151	EFFUSION PERICARDIAL		1	0.01			
152	ELECTROCARDIOGRAM ABNORMAL		6	0.05			
153	EMBOLISM PULMONARY		1	0.01			
154	EMBOLUS		1	0.01			
155	ENCEPHALOPATHY HYPERTENS		1	0.01			
156	EXTRASYSTOLES		1	0.01			
157	FIBRILLATION ATRIAL		2	0.02			
158	FIBRILLATION VENTRICULAR		1	0.01			
159	HEART ARREST		27	0.25			
160	HEART BLOCK		4	0.04			
161	HEART FAILURE		16	0.15			
162	HEART FAILURE CONGESTIVE		5	0.05			
163	HEART MALFORMATION		3	0.03			
164	HEMORRHAGE		41	0.37			
165	HEMORRHAGE CEREBRAL		4	0.04			
166	HEMORRHAGE SUBARACHNOID		3	0.03			
167	HYPERTENSION		131	1.19	L	L	No
168	HYPOTENSION		72	0.65			
169	HYPOTENSION POSTURAL		1	0.01			
170	INCREASED CAPILLARY FRAGILITY		1	0.01			
171	INFARCT CEREBRAL		1	0.01			
172	INFARCT MYOCARDIAL		1	0.01			
173	MIGRAINE		49	0.44			
174	MYOCARDIAL FIBROSIS		1	0.01			
175	MYOCARDIAL INFARCT		20	0.18			
176	MYOCARDITIS		1	0.01			
177	NECROSIS		1	0.01			
178	OCCLUSION		2	0.02			
179	PALLOR		12	0.11			

	A	B	C	D	E	F	G
180	PALPITATION		82	0.74	NL	L	Yes
181	PATENT DUCTUS ARTERIOSUS		1	0.01			
182	PERICARDIAL EFFUSION		4	0.04			
183	PERICARDITIS		6	0.05			
184	PERIPHERAL VASCULAR DISORDER		25	0.23			
185	PHLEBITIS		2	0.02			
186	POSTURAL HYPOTENSION		10	0.09			
187	PULMONARY EMBOLUS		14	0.13			
188	PULMONARY THROMBOSIS		2	0.02			
189	QT INTERVAL PROLONGED		4	0.04			
190	RETINAL ARTERY OCCLUSION		2	0.02			
191	RETINAL VEIN THROMBOSIS		2	0.02			
192	SINUS BRADYCARDIA		3	0.03			
193	SPIDER ANGIOMA		1	0.01			
194	ST DEPRESSED		1	0.01			
195	SUPRAVENTRICULAR TACHYCARDIA		1	0.01			
196	SYNCOPE		121	1.1	NL	L	Yes
197	T INVERTED		1	0.01			
198	TACHYCARDIA		71	0.64			
199	THROMBOPHLEBITIS		4	0.04			
200	THROMBOPHLEBITIS DEEP		1	0.01			
201	THROMBOSIS		11	0.1			
202	VARICOSE VEIN		2	0.02			
203	VASCULAR ANOMALY		4	0.04			
204	VASCULAR DISORDER		20	0.18			
205	VASCULAR DISORDER PERIPHERAL		1	0.01			
206	VASCULITIS		10	0.09			
207	VASODILATATION		98	0.89	L	L	No
208	VASOSPASM		1	0.01			
209	VENTRICULAR ARRHYTHMIA		3	0.03			
210	VENTRICULAR EXTRASYSTOLES		1	0.01			
211	VENTRICULAR FIBRILLATION		5	0.05			
212	VENTRICULAR SEPTAL DEFECT		3	0.03			
213	VENTRICULAR TACHYCARDIA		4	0.04			
214	**Sub Total**		**1197**				
215							

	A	B	C	D	E	F	G
216	***DIGESTIVE SYSTEM***						
217	ABNORMAL STOOLS		18	0.16			
218	ABSCESS		1	0.01			
219	ANOREXIA		125	1.13	L	L	No
220	APHTHOUS STOMATITIS		2	0.02			
221	APPETITE INCREASED		6	0.05			
222	BILIARY PAIN		2	0.02			
223	BLOODY DIARRHEA		3	0.03			
224	CARDIOSPASM		5	0.05			
225	CHEILITIS		8	0.07			
226	CHOLANGITIS		1	0.01			
227	CHOLECYSTITIS		9	0.08			
228	CHOLELITHIASIS		8	0.07			
229	CHOLESTATIC JAUNDICE		8	0.07			
230	CIRRHOSIS OF LIVER		4	0.04			
231	CLEFT LIP		2	0.02			
232	CLEFT PALATE		4	0.04			
233	COLITIS		30	0.27			
234	CONSTIPATION		114	1.03	L	L	No
235	DIARRHEA		250	2.27	L	L	No
236	DIARRHEA BLOODY		2	0.02			
237	DRY MOUTH		123	1.12	L	L	No
238	DUODENAL ULCER		3	0.03			
239	DUODENITIS		1	0.01			
240	DYSPEPSIA		125	1.13	L	L	No
241	DYSPHAGIA		51	0.46			
242	EDEMA TONGUE		3	0.03			
243	ENTERITIS		1	0.01			
244	ERUCTATION		15	0.14			
245	ESOPHAGEAL STENOSIS		1	0.01			
246	ESOPHAGEAL ULCER		1	0.01			
247	ESOPHAGITIS		16	0.15			
248	FECAL IMPACTION		2	0.02			
249	FECAL INCONTINENCE		19	0.17			
250	FLATULENCE		123	1.12	L	L	No

	A	B	C	D	E	F	G
216	***DIGESTIVE SYSTEM***						
217	ABNORMAL STOOLS		18	0.16			
218	ABSCESS		1	0.01			
219	ANOREXIA		125	1.13	L	L	No
220	APHTHOUS STOMATITIS		2	0.02			
221	APPETITE INCREASED		6	0.05			
222	BILIARY PAIN		2	0.02			
223	BLOODY DIARRHEA		3	0.03			
224	CARDIOSPASM		5	0.05			
225	CHEILITIS		8	0.07			
226	CHOLANGITIS		1	0.01			
227	CHOLECYSTITIS		9	0.08			
228	CHOLELITHIASIS		8	0.07			
229	CHOLESTATIC JAUNDICE		8	0.07			
230	CIRRHOSIS OF LIVER		4	0.04			
231	CLEFT LIP		2	0.02			
232	CLEFT PALATE		4	0.04			
233	COLITIS		30	0.27			
234	CONSTIPATION		114	1.03	L	L	No
235	DIARRHEA		250	2.27	L	L	No
236	DIARRHEA BLOODY		2	0.02			
237	DRY MOUTH		123	1.12	L	L	No
238	DUODENAL ULCER		3	0.03			
239	DUODENITIS		1	0.01			
240	DYSPEPSIA		125	1.13	L	L	No
241	DYSPHAGIA		51	0.46			
242	EDEMA TONGUE		3	0.03			
243	ENTERITIS		1	0.01			
244	ERUCTATION		15	0.14			
245	ESOPHAGEAL STENOSIS		1	0.01			
246	ESOPHAGEAL ULCER		1	0.01			
247	ESOPHAGITIS		16	0.15			
248	FECAL IMPACTION		2	0.02			
249	FECAL INCONTINENCE		19	0.17			
250	FLATULENCE		123	1.12	L	L	No

	A	B	C	D	E	F	G
251	GAMMA GLUTAMYL TRANSPEPTIDASE INCREASED		33	0.3			
252	GASTRITIS		11	0.1			
253	GASTROENTERITIS		3	0.03			
254	GASTROINTESTINAL CARCINOMA		5	0.05			
255	GASTROINTESTINAL DISORDER		69	0.63			
256	GASTROINTESTINAL HEMORRHAGE		12	0.11			
257	GINGIVITIS		81	0.74			
258	GLOSSITIS		25	0.23			
259	GUM HEMORRHAGE		38	0.34			
260	GUM HYPERPLASIA		13	0.12			
261	HEMATEMESIS		4	0.04			
262	HEMORRHAGE GI		1	0.01			
263	HEMORRHAGE RECTAL		3	0.03			
264	HEMORRHAGIC COLITIS		1	0.01			
265	HEPATIC COMA		1	0.01			
266	HEPATIC FAILURE		4	0.04			
267	HEPATIC NEOPLASIA		3	0.03			
268	HEPATITIS		31	0.28			
269	HEPATITIS B POSITIVE SA		3	0.03			
270	HEPATOMA		1	0.01			
271	HEPATOMEGALY		6	0.05			
272	HEPATOSPLENOMEGALY		1	0.01			
273	HYPERPLASIA GUM		4	0.04			
274	ILEITIS		1	0.01			
275	ILEUS		2	0.02			
276	IMPERFORATE ANUS		1	0.01			
277	INCONTINENCE FECAL		5	0.05			
278	INCREASED APPETITE		63	0.57			
279	INCREASED SALIVATION		20	0.18			
280	INTESTINAL NECROSIS		1	0.01			
281	INTESTINAL OBSTRUCTION		6	0.05			
282	INTESTINAL PERFORATION		2	0.02			
283	INTESTINAL ULCER		1	0.01			
284	JAUNDICE		16	0.15			
285	LEUKOPLAKIA OF MOUTH		3	0.03			

	A	B	C	D	E	F	G
286	LIVER DAMAGE		21	0.19			
287	LIVER FATTY DEPOSIT		3	0.03			
288	LIVER FUNCT TEST ABNOR		12	0.11			
289	LIVER FUNCTION TESTS ABNORMAL		100	0.91			**No - Labeled for elevtaed LFTs**
290	LIVER NECROSIS		1	0.01			
291	LIVER TENDERNESS		1	0.01			
292	MALABSORPTION SYNDROME		7	0.06			
293	MEGACOLON		1	0.01			
294	MELENA		17	0.15			
295	MOUTH ULCERATION		25	0.23			
296	NAUSEA		385	3.49	L	L	No
297	NAUSEA AND VOMITING		43	0.39			
298	NAUSEA/VOMITING		7	0.06			
299	NECROTIZING PANCREATITIS		2	0.02			
300	ORAL MONILIASIS		4	0.04			
301	PANCREAS DISORDER		2	0.02			
302	PANCREATITIS		45	0.41			
303	PAROTID GLAND ENLARGEMENT		1	0.01			
304	PEPTIC ULCER		1	0.01			
305	PERIODONTAL ABSCESS		5	0.05			
306	PERIODONTITIS		4	0.04			
307	PHARYNGITIS		3	0.03			
308	PROCTITIS		2	0.02			
309	PSEUDOMEMBRANOUS COLITIS		1	0.01			
310	RECTAL DISORDER		11	0.1			
311	RECTAL HEMORRHAGE		13	0.12			
312	SALIVARY GLAND ENLARGEMENT		3	0.03			
313	SALIVATION INCREASED		2	0.02			
314	SIALADENITIS		1	0.01			
315	STOMACH ATONY		3	0.03			
316	STOMACH ULCER		7	0.06			
317	STOMATITIS		49	0.44			
318	STOOLS ABNORMAL		1	0.01			

	A	B	C	D	E	F	G
319	TENESMUS		1	0.01			
320	THIRST		17	0.15			
321	TONGUE DISCOLORATION		7	0.06			
322	TONGUE DISORDER		16	0.15			
323	TONGUE EDEMA		28	0.25			
324	TOOTH CARIES		15	0.14			
325	TOOTH DISCOLORATION		18	0.16			
326	TOOTH DISORDER		47	0.43			
327	ULCER MOUTH		2	0.02			
328	ULCER STOMACH W/HEMORRHAGE		1	0.01			
329	ULCERATIVE COLITIS		2	0.02			
330	ULCERATIVE STOMATITIS		9	0.08			
331	VOMITING		154	1.4	L	L	No
332	**Sub Total**		**2660**				
333							
334	***DRUG, CHARACTER***						
335	PRODUCT CHARACTERISTICS		1	0.01			
336	**Sub Total**		**1**				
337							
338	***DRUG, USAGE***						
339	OFF-LABEL USE OF DRUG		3189	28.94			
340	**Sub Total**		**3189**				
341							
342	***ENDOCRINE SYSTEM***						
343	ACCELERATED SEXUAL MATURITY		1	0.01			
344	ADH INAPPROPRIATE		8	0.07			
345	ADRENAL CORTEX INSUFFIENCY		3	0.03			
346	CUSHINGS SYNDROME		4	0.04			
347	DIABETES MELLITUS		29	0.26			
348	DIABETIC COMA		1	0.01			
349	ENDOCRINE DISORDER		1	0.01			
350	FERTILITY DECR MALE		1	0.01			
351	FERTILITY DECREASED MALE		6	0.05			
352	GOITER		4	0.04			
353	GONADOTROPIC FOLLICLE STIM HORMONE INCRE		1	0.01			

	A	B	C	D	E	F	G
354	HYPERTHYROIDISM		6	0.05			
355	HYPOTHYROIDISM		17	0.15			
356	NEOPLASM		1	0.01			
357	PARATHYROID DISORDER		3	0.03			
358	PITUITARY ACTIVITY INCREASED		2	0.02			
359	PROLACTIN INCREASED		13	0.12			
360	THYROID CARCINOMA		1	0.01			
361	THYROID DISORDER		5	0.05			
362	THYROIDITIS		3	0.03			
363	**Sub Total**		**110**				
364							
365	***FETAL AND NEONATAL DISORDERS***						
366	ANOMALY CONGENITAL		1	0.01			
367	**Sub Total**		**1**				
368							
369	***HEMIC & LYMPHATIC SYSTEM***						
370	ABNORMAL PLATELETS		2	0.02			
371	ACUTE LEUKEMIA		1	0.01			
372	ACUTE LYMPHOBLASTIC LEUKEMIA		1	0.01			
373	AGRANULOCYTOSIS		7	0.06			
374	ANA POSITIVE		3	0.03			
375	ANEMIA		52	0.47			
376	ANEMIA APLASTIC		1	0.01			
377	ANEMIA HEMOLYTIC		2	0.02			
378	ANEMIA HYPOCHROMIC		1	0.01			
379	ANEMIA IRON DEFICIENCY		1	0.01			
380	ANTINUCLEAR ANTIBODY PRESENT		10	0.09			
381	APLASTIC ANEMIA		4	0.04			
382	BASOPHILIA		1	0.01			
383	BLEEDING TIME DECREASED		1	0.01			
384	BLEEDING TIME INCREASED		9	0.08			
385	COAGULATION DISORDER		9	0.08			
386	COAGULATION TIME DECREASED		8	0.07			
387	COAGULATION TIME INCREASED		11	0.1			
388	CYANOSIS		9	0.08			
389	ECCHYMOSIS		92	0.83			Yes

	A	B	C	D	E	F	G
390	EOSINOPHILIA		8	0.07			
391	ERYTHROCYTES ABNORMAL		4	0.04			
392	ESR INCREASED		1	0.01			
393	HEMOLYSIS		1	0.01			
394	HEMOLYTIC ANEMIA		5	0.05			
395	HYPERVOLEMIA		1	0.01			
396	HYPOCHROMIC ANEMIA		23	0.21			
397	HYPOVOLEMIA		3	0.03			
398	IRON DEFICIENCY ANEMIA		2	0.02			
399	LEUKEMIA		2	0.02			
400	LEUKEMOID REACTION		4	0.04			
401	LEUKOCYTOSIS		17	0.15			
402	LEUKOPENIA		123	1.12	L	L	No
403	LYMPHADENOPATHY		18	0.16			
404	LYMPHEDEMA		1	0.01			
405	LYMPHOCYTOSIS		5	0.05			
406	LYMPHOMA LIKE REACTION		7	0.06			
407	LYMPHOMA-LIKE REACTION		1	0.01			
408	MACROCYTIC ANEMIA		2	0.02			
409	MARROW DEPRESSION		3	0.03			
410	MEGALOBLASTIC ANEMIA		1	0.01			
411	MICROCYTIC ANEMIA		2	0.02			
412	MONOCYTOSIS		2	0.02			
413	MYELOMA		4	0.04			
414	PANCYTOPENIA		8	0.07			
415	PETECHIA		4	0.04			
416	PLATELETS ABNORMAL		2	0.02			
417	PROTHROMBIN DECREASED		29	0.26			
418	PROTHROMBIN INCREASED		9	0.08			
419	PURPURA		18	0.16			
420	SEDIMENTATION RATE INCREASED		10	0.09			
421	SPLENOMEGALY		1	0.01			
422	SYPHILIS TEST FALSE POSITIVE		1	0.01			
423	THROMBOCYTHEMIA		3	0.03			
424	THROMBOCYTOPENIA		88	0.8			
425	THROMBOCYTOPENIC PURPURA		6	0.05			

	A	B	C	D	E	F	G
456	HYPERGLYCEMIA		102	0.93			No - Labeled for blood glucose fluctuations
457	HYPERKALEMIA		9	0.08			
458	HYPERLIPEMIA		13	0.12			
459	HYPERNATREMIA		5	0.05			
460	HYPERPHOSPHATEMIA		3	0.03			
461	HYPERURICEMIA		1	0.01			
462	HYPOCALCEMIA		3	0.03			
463	HYPOCHLOREMIA		1	0.01			
464	HYPOCHOLESTEREMIA		2	0.02			
465	HYPOGLYCEMIA		47	0.43			
466	HYPOGLYCEMIC REACTION		1	0.01			
467	HYPOKALEMIA		11	0.1			
468	HYPOLIPEMIA		1	0.01			
469	HYPOMAGNESEMIA		2	0.02			
470	HYPONATREMIA		34	0.31			
471	HYPOPROTEINEMIA		3	0.03			
472	KETOSIS		4	0.04			
473	LACTIC ACIDOSIS		1	0.01			
474	LACTIC DEHYDROGENASE INCREASED		6	0.05			
475	NPN INCREASED		12	0.11			
476	OBESITY		1	0.01			
477	PERIPHERAL EDEMA		381	3.46	L	L	No
478	PHOSPHATASE ALKALINE INCREASED		1	0.01			
479	PORPHYRIA		1	0.01			
480	RESPIRATORY ACIDOSIS		3	0.03			
481	SGOT (AST) INCREASED		3	0.03			
482	SGOT INCREASED		41	0.37			
483	SGPT (ALT) INCREASED		2	0.02			
484	SGPT INCREASED		48	0.44			
485	WATER INTOXICATION		1	0.01			
486	WEIGHT GAIN		464	4.21	L	L	No
487	WEIGHT LOSS		107	0.97	NL	L	Yes
488	**Sub Total**		**1629**				

	A	B	C	D	E	F	G
489							
490	***MUSCULOSKELETAL SYSTEM***						
491	ARTHRALGIA		159	1.44	L	L	No
492	ARTHRITIS		48	0.44			
493	ARTHROSIS		42	0.38			
494	BONE DISORDER		21	0.19			
495	BONE FRACTURE		18	0.16			
496	BONE NECROSIS		3	0.03			
497	BONE NEOPLASM		2	0.02			
498	BONE PAIN		9	0.08			
499	BURSITIS		2	0.02			
500	GENERALIZED SPASM		9	0.08			
501	INFECTION		1	0.01			
502	JOINT DISORDER		61	0.55			
503	LEG CRAMPS		22	0.2			
504	MUSCLE ATROPHY		6	0.05			
505	MUSCULOSKELETAL CONGENITAL ANOMALY		7	0.06			
506	MYALGIA		130	1.18	L	L	No
507	MYASTHENIA		100	0.91			Yes
508	MYOPATHY		11	0.1			
509	MYOSITIS		1	0.01			
510	OSTEOMALACIA		1	0.01			
511	OSTEOMYELITIS		3	0.03			
512	OSTEOPOROSIS		14	0.13			
513	PAIN BACK		1	0.01			
514	PATHOLOGICAL FRACTURE		1	0.01			
515	RHEUMATOID ARTHRITIS		3	0.03			
516	SYNOVITIS		2	0.02			
517	TENDINOUS CONTRACTURE		2	0.02			
518	TENDON DISORDER		5	0.05			
519	TENDON RUPTURE		1	0.01			
520	TENOSYNOVITIS		5	0.05			
521	**Sub Total**		**690**				
522							
523	***NERVOUS SYSTEM***						
524	ABNORMAL DREAMS		49	0.44			

	A	B	C	D	E	F	G
525	ABNORMAL ELECTROENCEPHALOGRAM		11	0.1			
526	ABNORMAL GAIT		129	1.17	L	NL	No
527	ACUTE BRAIN SYNDROME		7	0.06			
528	ADDICTION		9	0.08			
529	AGITATION		101	0.92	NL	L	Yes
530	AKATHISIA		5	0.05			
531	AKINESIA		1	0.01			
532	AMNESIA		301	2.73	L	L	No
533	ANTISOCIAL REACTION		6	0.05			
534	ANXIETY		213	1.93	L	L	No
535	APATHY		18	0.16			
536	APHASIA		16	0.15			
537	ATAXIA		252	2.29	L	L	No
538	BRAIN EDEMA		5	0.05			
539	BRAIN STEM DISORDER		1	0.01			
540	BRAIN SYNDROME ACUTE		1	0.01			
541	BUCCOGLOSSAL SYNDROME		4	0.04			
542	CARCINOMA		3	0.03			
543	CATATONIC REACTION		4	0.04			
544	CEREBELLAR ATAXIA		1	0.01			
545	CEREBELLAR SYNDROME		2	0.02			
546	CHOREOATHETOSIS		26	0.24			
547	CHRONIC BRAIN SYNDROME		2	0.02			
548	CIRCUMORAL PARESTHESIA		8	0.07			
549	CNS CONGENITAL ANOMALY		3	0.03			
550	CNS DEPRESSION		7	0.06			
551	CNS NEOPLASIA		11	0.1			
552	CNS STIMULATION		3	0.03			
553	COGWHEEL RIGIDITY		1	0.01			
554	COMA		34	0.31			
555	CONFUSION		318	2.89	L	L	No
556	CONVULSION		802	7.28	L	L	No
557	CONVULSION GRAND MAL		44	0.4			
558	COORDINATION ABNORMAL		26	0.24			
559	DELIRIUM		12	0.11			
560	DELUSIONS		19	0.17			

	A	B	C	D	E	F	G
561	DEMENTIA		13	0.12			
562	DEPERSONALIZATION		98	0.89	NL	L	Yes
563	DEPRESSION		242	2.2	L	L	No
564	DEPRESSION PSYCHOTIC		4	0.04			
565	DIPLOPIA		17	0.15			
566	DIZZINESS		786	7.13	L	L	No
567	DREAMS ABNORMAL		4	0.04			
568	DRUG DEPENDENCE		156	1.42			?
569	DYSARTHRIA		25	0.23			
570	DYSAUTONOMIA		1	0.01			
571	DYSKINESIA		16	0.15			
572	DYSTONIA		23	0.21			
573	EEG ABNORMAL		1	0.01			
574	EMOTIONAL LABILITY		125	1.13	L	L	No
575	ENCEPHALITIS		2	0.02			
576	ENCEPHALOPATHY		16	0.15			
577	EUPHORIA		39	0.35			
578	EXTRAPYRAMIDAL SYNDROME		18	0.16			
579	FACIAL PARALYSIS		21	0.19			
580	FLACCID PARALYSIS		1	0.01			
581	GAIT ABNORMAL		10	0.09			
582	GRAND MAL CONVULSION		52	0.47			
583	HALLUCINATIONS		157	1.42	NL	L	Yes
584	HEMATOMA SUBDURAL		4	0.04			
585	HEMIPLEGIA		8	0.07			
586	HOSTILITY		196	1.78	L	L	No
587	HYPALGESIA		1	0.01			
588	HYPERALGESIA		1	0.01			
589	HYPERESTHESIA		13	0.12			
590	HYPERKINESIA		65	0.59			
591	HYPERTONIA		101	0.92			Yes
592	HYPESTHESIA		128	1.16	L	L	No
593	HYPOKINESIA		61	0.55			
594	HYPOTONIA		14	0.13			
595	HYSTERIA		11	0.1			

	A	B	C	D	E	F	G
596	INCOORDINATION		140	1.27			Labeled for coordination abnormal
597	INSOMNIA		262	2.38	L	L	No
598	INTRACRANIAL HEMORRHAGE		3	0.03			
599	INTRACRANIAL HYPERTENSION		5	0.05			
600	LIBIDO DECREASED		74	0.67			
601	LIBIDO INCREASED		16	0.15			
602	MANIA		2	0.02			
603	MANIC DEPRESSIVE REACTION		9	0.08			
604	MANIC REACTION		53	0.48			
605	MENINGITIS		4	0.04			
606	MENTAL RETARDATION		1	0.01			
607	MOVEMENT DISORDER		35	0.32			
608	MULTIPLE SCLEROSIS		7	0.06			
609	MYELITIS		1	0.01			
610	MYOCLONUS		55	0.5			
611	NEOPLASM		2	0.02			
612	NERVOUSNESS		230	2.09	L	L	No
613	NEURALGIA		25	0.23			
614	NEURITIS		2	0.02			
615	NEUROPATHY		93	0.84			
616	NEUROSIS		13	0.12			
617	NYSTAGMUS		32	0.29			
618	OCULOGYRIC CRISIS		1	0.01			
619	OPISTHOTONOS		1	0.01			
620	PARALYSIS		19	0.17			
621	PARALYSIS FACIAL		1	0.01			
622	PARANOID REACTION		36	0.33			
623	PARESTHESIA		227	2.06	L	L	No
624	PERIPHERAL NEURITIS		10	0.09			
625	PERSONALITY DISORDER		167	1.52	NL	L	Yes
626	POLYNEURITIS		1	0.01			
627	PORENCEPHALY		1	0.01			
628	PSYCHOSIS		72	0.65			
629	REFLEXES DECREASED		7	0.06			

	A	B	C	D	E	F	G
630	REFLEXES INCREASED		2	0.02			
631	SCHIZOPHRENIC REACTION		8	0.07			
632	SCREAMING SYNDROME		2	0.02			
633	SLEEP DISORDER		37	0.34			
634	SOMNOLENCE		948	8.6	L	L	No
635	SPEECH DISORDER		219	1.99	NL	NL	Yes
636	STUPOR		108	0.98	NL	L	Yes
637	SUBDURAL HEMATOMA		5	0.05			
638	TARDIVE DYSKINESIA		2	0.02			
639	THINKING ABNORMAL		315	2.86	L	L	No
640	TORTICOLLIS		1	0.01			
641	TREMOR		295	2.68	L	L	No
642	TWITCHING		158	1.43	L	L	No
643	VERTIGO		98	0.89			
644	VESTIBULAR DISORDER		3	0.03			
645	WITHDRAWAL SYNDROME		118	1.07			**Wording to be added**
646	**Sub Total**		**8811**				
647							
648	***RESPIRATORY SYSTEM***						
649	ABSCESS		1	0.01			
650	APNEA		31	0.28			
651	ASPHYXIA		1	0.01			
652	ASPIRATION PNEUMONIA		7	0.06			
653	ASTHMA		35	0.32			
654	ATELECTASIS		3	0.03			
655	BRONCHITIS		31	0.28			
656	CARCINOMA LUNG		2	0.02			
657	CARCINOMA OF LARYNX		1	0.01			
658	CARCINOMA OF LUNG		3	0.03			
659	COUGH INCREASED		54	0.49			
660	DYSPNEA		151	1.37	L	L	No
661	EDEMA LUNG		1	0.01			
662	EFFUSION PLEURAL		1	0.01			
663	EMPHYSEMA		2	0.02			
664	EPISTAXIS		37	0.34			

	A	B	C	D	E	F	G
665	HEMOPTYSIS		8	0.07			
666	HICCUP		6	0.05			
667	HYPERVENTILATION		14	0.13			
668	HYPOVENTILATION		16	0.15			
669	HYPOXIA		8	0.07			
670	INTERSTITIAL PNEUMONIA		5	0.05			
671	LARYNGITIS		12	0.11			
672	LUNG DISORDER		21	0.19			
673	LUNG EDEMA		23	0.21			
674	LUNG FIBROSIS		7	0.06			
675	LUNG FUNCT ABNORMAL		2	0.02			
676	LUNG HEMORRHAGE		2	0.02			
677	PHARYNGITIS		67	0.61			
678	PLEURAL DISORDER		1	0.01			
679	PLEURAL EFFUSION		5	0.05			
680	PNEUMONIA		98	0.89	L	L	No
681	PNEUMONIA ASPIRATION		6	0.05			
682	PULMONARY HYPERTENSION		2	0.02			
683	RESPIRATORY CONGENITAL ANOMALY		2	0.02			
684	RESPIRATORY DISORDER		27	0.25			
685	RESPIRATORY DISTRESS SYNDROME		1	0.01			
686	RHINITIS		40	0.36			
687	SINUSITIS		20	0.18			
688	SPUTUM INCREASED		5	0.05			
689	VOICE ALTERATION		11	0.1			
690	YAWN		2	0.02			
691	**Sub Total**		**772**				
692							
693	***SKIN AND APPENDAGES***						
694	ACNE		34	0.31			
695	ALOPECIA		332	3.01	NL	L	Yes
696	ANGIOEDEMA		21	0.19			
697	CHLOASMA		1	0.01			
698	CONTACT DERMATITIS		2	0.02			
699	DISCOID LUPUS ERYTHEMATOSIS		1	0.01			
700	DRY SKIN		31	0.28			

	A	B	C	D	E	F	G
701	ECZEMA		21	0.19			
702	EPIDERMAL NECROLYSIS		4	0.04			
703	ERYTHEMA MULTIFORME		15	0.14			
704	EXFOLIATIVE DERMATITIS		19	0.17			
705	FUNGAL DERMATITIS		1	0.01			
706	FURUNCULOSIS		2	0.02			
707	HAIR DISCOLORATION		3	0.03			
708	HAIR DISORDER		18	0.16			
709	HERPES SIMPLEX		8	0.07			
710	HERPES ZOSTER		20	0.18			
711	HIRSUTISM		16	0.15			
712	HYPERTROPHY SKIN		1	0.01			
713	LEUKODERMA		3	0.03			
714	LICHENOID DERMATITIS		2	0.02			
715	MACULOPAPULAR RASH		26	0.24			
716	MELANOSIS		4	0.04			
717	NAIL DISORDER		16	0.15			
718	NEOPLASM SKIN BENIGN		3	0.03			
719	PRURITUS		170	1.54	L	L	No
720	PSORIASIS		11	0.1			
721	PURPURIC RASH		4	0.04			
722	PUSTULAR RASH		3	0.03			
723	RASH		411	3.73	L	L	No
724	RASH MACULOPAPULAR		4	0.04			
725	RASH PURPURIC		1	0.01			
726	RASH PUSTULAR		2	0.02			
727	RASH VESICULOBULLOUS		3	0.03			
728	SEBORRHEA		3	0.03			
729	SKIN BENIGN NEOPLASM		1	0.01			
730	SKIN DISCOLORATION		35	0.32			
731	SKIN DISORDER		38	0.34			
732	SKIN DRY		3	0.03			
733	SKIN HYPERTROPHY		1	0.01			
734	SKIN NECROSIS		2	0.02			
735	SKIN NODULE		6	0.05			
736	SKIN ULCER		5	0.05			

	A	B	C	D	E	F	G
701	ECZEMA		21	0.19			
702	EPIDERMAL NECROLYSIS		4	0.04			
703	ERYTHEMA MULTIFORME		15	0.14			
704	EXFOLIATIVE DERMATITIS		19	0.17			
705	FUNGAL DERMATITIS		1	0.01			
706	FURUNCULOSIS		2	0.02			
707	HAIR DISCOLORATION		3	0.03			
708	HAIR DISORDER		18	0.16			
709	HERPES SIMPLEX		8	0.07			
710	HERPES ZOSTER		20	0.18			
711	HIRSUTISM		16	0.15			
712	HYPERTROPHY SKIN		1	0.01			
713	LEUKODERMA		3	0.03			
714	LICHENOID DERMATITIS		2	0.02			
715	MACULOPAPULAR RASH		26	0.24			
716	MELANOSIS		4	0.04			
717	NAIL DISORDER		16	0.15			
718	NEOPLASM SKIN BENIGN		3	0.03			
719	PRURITUS		170	1.54	L	L	No
720	PSORIASIS		11	0.1			
721	PURPURIC RASH		4	0.04			
722	PUSTULAR RASH		3	0.03			
723	RASH		411	3.73	L	L	No
724	RASH MACULOPAPULAR		4	0.04			
725	RASH PURPURIC		1	0.01			
726	RASH PUSTULAR		2	0.02			
727	RASH VESICULOBULLOUS		3	0.03			
728	SEBORRHEA		3	0.03			
729	SKIN BENIGN NEOPLASM		1	0.01			
730	SKIN DISCOLORATION		35	0.32			
731	SKIN DISORDER		38	0.34			
732	SKIN DRY		3	0.03			
733	SKIN HYPERTROPHY		1	0.01			
734	SKIN NECROSIS		2	0.02			
735	SKIN NODULE		6	0.05			
736	SKIN ULCER		5	0.05			

	A	B	C	D	E	F	G
737	STEVENS JOHNSON SYNDROME		17	0.15			
738	STEVENS-JOHNSON SYNDROME		1	0.01			
739	SUBCUTANEOUS NODULE		2	0.02			
740	SWEATING		107	0.97	NL		Yes - Sweating increased labeled in USPI
741	SWEATING DECREASED		1	0.01			
742	URTICARIA		88	0.8	NL	L	Yes
743	VESICULOBULLOUS RASH		36	0.33			
744	**Sub Total**		**1559**				
745							
746	***SPECIAL SENSES***						
747	ABNORMAL VISION		226	2.05	L	L	No
748	ABNORMALITY OF ACCOMMODATION		4	0.04			
749	AMBLYOPIA		268	2.43	L	L	No
750	ANISOCORIA		1	0.01			
751	BLINDNESS		13	0.12			
752	CATARACT NOS		3	0.03			
753	CATARACT SPECIFIED		19	0.17			
754	CHROMATOPSIA		1	0.01			
755	COLOR BLINDNESS		3	0.03			
756	CONJUNCTIVITIS		25	0.23			
757	CORNEAL LESION		5	0.05			
758	CORNEAL OPACITY		2	0.02			
759	DEAFNESS		65	0.59			
760	DIPLOPIA		94	0.85			
761	DRY EYES		25	0.23			
762	EAR DISORDER		22	0.2			
763	EAR PAIN		24	0.22			
764	EXTRAOCULAR PALSY		3	0.03			
765	EYE DISORDER		65	0.59			
766	EYE HEMORRHAGE		10	0.09			
767	EYE PAIN		42	0.38			
768	GLAUCOMA		5	0.05			

	A	B	C	D	E	F	G
769	HEMORRHAGE EYE		1	0.01			
770	HYPERACUSIS		6	0.05			
771	IRITIS		3	0.03			
772	KERATITIS		3	0.03			
773	LACRIMATION DISORDER		19	0.17			
774	MIOSIS		4	0.04			
775	MYDRIASIS		11	0.1			
776	NIGHT BLINDNESS		2	0.02			
777	OPTIC ATROPHY		6	0.05			
778	OPTIC NEURITIS		4	0.04			
779	OTITIS EXTERNA		2	0.02			
780	OTITIS MEDIA		14	0.13			
781	PAPILLEDEMA		2	0.02			
782	PAROSMIA		29	0.26			
783	PHOTOPHOBIA		24	0.22			
784	PTOSIS		4	0.04			
785	PUPILLARY DISORDER		1	0.01			
786	REFRACTION DISORDER		10	0.09			
787	RETINAL DEGENERATION		3	0.03			
788	RETINAL DETACHMENT		1	0.01			
789	RETINAL DISORDER		14	0.13			
790	RETINAL EDEMA		2	0.02			
791	RETINAL HEMORRHAGE		4	0.04			
792	RETINAL PIGMENTATION		1	0.01			
793	RETROBULBAR NEURITIS		1	0.01			
794	STRABISMUS		4	0.04			
795	TASTE LOSS		26	0.24			
796	TASTE PERVERSION		50	0.45			
797	TINNITUS		73	0.66	NL	L	Yes
798	UVEITIS		1	0.01			
799	VISION ABNORMAL		13	0.12			
800	VISUAL FIELD DEFECT		28	0.25			
801	VITREOUS DISORDER		8	0.07			
802	**Sub Total**		**1299**				
803							
804	***UROGENITAL SYSTEM***						

	A	B	C	D	E	F	G
805	ABNORMAL EJACULATION		21	0.19			
806	ABNORMAL LABOR		3	0.03			
807	ABORTION		25	0.23			
808	ACUTE KIDNEY FAILURE		19	0.17			
809	ALBUMINURIA		10	0.09			
810	AMENORRHEA		31	0.28			
811	ANORGASMIA		33	0.3			
812	BILIRUBINURIA		1	0.01			
813	BIRTH PREMATURE		1	0.01			
814	BREAST ABSCESS		1	0.01			
815	BREAST ATROPHY		2	0.02			
816	BREAST CARCINOMA		4	0.04			
817	BREAST ENGORGEMENT		2	0.02			
818	BREAST ENLARGEMENT		7	0.06			
819	BREAST NEOPLASM		6	0.05			
820	BREAST PAIN		20	0.18			
821	CARCINOMA BREAST		2	0.02			
822	CARCINOMA CERVIX IN SITU		1	0.01			
823	CERVIX CARCINOMA		1	0.01			
824	CREATININE CLEARANCE DECREASED		2	0.02			
825	CYST		3	0.03			
826	CYSTITIS		15	0.14			
827	DYSMENORRHEA		6	0.05			
828	DYSURIA		22	0.2			
829	EJACULATION ABNORMAL		1	0.01			
830	ENDOMETRIAL CARCINOMA		2	0.02			
831	ENDOMETRIAL DISORDER		5	0.05			
832	ENDOMETRIAL HYPERPLASIA		2	0.02			
833	EPIDIDYMITIS		1	0.01			
834	FEMALE LACTATION		14	0.13			
835	FIBROCYSTIC BREAST		2	0.02			
836	GLYCOSURIA		1	0.01			
837	GYNECOMASTIA		16	0.15			
838	HEMATURIA		32	0.29			
839	HEMORRHAGIC CYSTITIS		1	0.01			
840	HYDRONEPHROSIS		2	0.02			

	A	B	C	D	E	F	G
841	HYPOMENORRHEA		5	0.05			
842	IMPOTENCE		94	0.85	L	L	No
843	INCONTINENCE URINARY		13	0.12			
844	INFECTION URINARY TRACT		5	0.05			
845	KIDNEY CALCULUS		13	0.12			
846	KIDNEY FAILURE		18	0.16			
847	KIDNEY FAILURE ACUTE		5	0.05			
848	KIDNEY FUNCTION ABNORMAL		34	0.31			
849	KIDNEY PAIN		12	0.11			
850	KIDNEY TUBULAR NECROSIS		1	0.01			
851	LACTATION DECREASED		2	0.02			
852	LACTATION MALE		1	0.01			
853	LEUKORRHEA		2	0.02			
854	MALE LACTATION		1	0.01			
855	MENOPAUSE		1	0.01			
856	MENORRHAGIA		14	0.13			
857	MENSTRUAL DISORDER		11	0.1			
858	METRORRHAGIA		33	0.3			
859	NECROSIS KIDNEY CORTEX		1	0.01			
860	NECROSIS KIDNEY TUBULES		1	0.01			
861	NEOPLASM BREAST		2	0.02			
862	NEPHRITIS		6	0.05			
863	NEPHROSIS		5	0.05			
864	NOCTURIA		3	0.03			
865	OLIGURIA		7	0.06			
866	OVARIAN DISORDER		3	0.03			
867	PAIN		1	0.01			
868	PAIN BREAST		2	0.02			
869	PAPANICOLAU SMEAR SUSPICIOUS		1	0.01			
870	PENIS DISORDER		2	0.02			
871	POLYCYSTIC KIDNEY		1	0.01			
872	POLYURIA		7	0.06			
873	PREGNANCY DISORDER		4	0.04			
874	PREGNANCY UNINTENDED		5	0.05			
875	PREMATURE BIRTH		4	0.04			
876	PRIAPISM		5	0.05			

	A	B	C	D	E	F	G
877	PROSTATIC CARCINOMA		5	0.05			
878	PROSTATIC DISORDER		5	0.05			
879	PROSTATIC SPECIFIC ANTIGEN INCREASE		8	0.07			
880	PYELONEPHRITIS		3	0.03			
881	PYURIA		1	0.01			
882	SCROTAL EDEMA		3	0.03			
883	STILLBIRTH		6	0.05			
884	TESTIS DISORDER		4	0.04			
885	UNINTENDED PREGNANCY		10	0.09			
886	URETHRAL PAIN		2	0.02			
887	URINARY FREQUENCY		52	0.47			
888	URINARY INCONTINENCE		76	0.69			
889	URINARY RETENTION		38	0.34			
890	URINARY TRACT DISORDER		18	0.16			
891	URINARY TRACT INFECTION		44	0.4			
892	URINARY URGENCY		10	0.09			
893	URINATION IMPAIRED		22	0.2			
894	URINE ABNORMALITY		40	0.36			
895	UROGENITAL ANOMALY		6	0.05			
896	UROGENITAL DISORDER		1	0.01			
897	UTERINE DISORDER		1	0.01			
898	UTERINE FIBROIDS DEGENERATED		1	0.01			
899	UTERINE HEMORRHAGE		2	0.02			
900	UTERINE NEOPLASM		1	0.01			
901	VAGINAL HEMORRHAGE		16	0.15			
902	VAGINITIS		5	0.05			
903	VULVOVAGINAL DISORDER		1	0.01			
904	**Sub Total**		**1023**				
905							
906	**Total Number of Events**	**29256**					
907							
908	**Total Number of Cases**	**11020**					

Altman April 3, 2008 Declaration

Exhibit Altman-F

High Level Terms Greater that 1% of Serious Adverse Event Reports Through March 31, 2002

High Level Term	Reports	% Reports (2420 Total)
Therapeutic and nontherapeutic responses	622	25.70%
Seizures and seizure disorders NEC	387	15.99%
Disturbances in consciousness NEC	216	8.93%
Overdoses	175	7.23%
General signs and symptoms NEC	148	6.12%
Asthenic conditions	139	5.74%
Neurological signs and symptoms NEC	138	5.70%
Death and sudden death	126	5.21%
Confusion and disorientation	115	4.75%
Non-site specific injuries NEC	109	4.50%
Interactions	103	4.26%
Nausea and vomiting symptoms	103	4.26%
Cerebellar coordination and balance disturbances	103	4.26%
Physical examination procedures	102	4.21%
Pain and discomfort NEC	101	4.17%
Lower respiratory tract and lung infections	99	4.09%
Breathing abnormalities	90	3.72%
Anxiety symptoms	86	3.55%
Oedema NEC	80	3.31%
Depressive disorders	78	3.22%
Liver function analyses	78	3.22%
Headaches NEC	75	3.10%
Tremor (excl congenital)	74	3.06%
Maladministration and accidental exposure	72	2.98%
Musculoskeletal and connective tissue signs and symptoms NEC	72	2.98%
Speech and language abnormalities	67	2.77%
Therapeutic drug monitoring analyses	63	2.60%
Memory loss (excl dementia)	60	2.48%
Renal failure and impairment	60	2.48%
Partial vision loss	59	2.44%
Febrile disorders	54	2.23%
Visual disorders NEC	54	2.23%
Paraesthesias and dysaesthesias	54	2.23%
Gastrointestinal and abdominal pains (excl oral and throat)	53	2.19%
Central nervous system haemorrhages and cerebrovascular accidents	52	2.15%
Behaviour and socialisation disturbances	48	1.98%
Suicidal and self-injurious behaviour	45	1.86%
Rashes, eruptions and exanthems NEC	45	1.86%
Perception disturbances	44	1.82%
Joint related signs and symptoms	44	1.82%

Disturbances in initiating and maintaining sleep	41	1.69%
Mental impairment (excl dementia and memory loss)	40	1.65%
Hepatocellular damage and hepatitis NEC	40	1.65%
Acute and chronic pancreatitis	39	1.61%
Psychotic disorder NEC	38	1.57%
Diarrhoea (excl infective)	38	1.57%
Urinary tract infections	38	1.57%
Poisoning and toxicity	37	1.53%
Dyskinesias and movement disorders NEC	37	1.53%
Thrombocytopenias	36	1.49%
Rate and rhythm disorders NEC	36	1.49%
Vascular hypotensive disorders	35	1.45%
Bladder and urethral symptoms	35	1.45%
Heart failures NEC	34	1.40%
Ischaemic coronary artery disorders	34	1.40%
Muscle related signs and symptoms NEC	34	1.40%
Coma states	34	1.40%
Anaemias NEC	33	1.36%
Gastrointestinal signs and symptoms NEC	33	1.36%
Appetite disorders	32	1.32%
Ventricular arrhythmias and cardiac arrest	32	1.32%
Generalised tonic-clonic seizures	32	1.32%
Disability issues	31	1.28%
Gait disturbances	31	1.28%
White blood cell analyses	30	1.24%
Gastrointestinal atonic and hypomotility disorders NEC	30	1.24%
Pruritus NEC	30	1.24%
Sepsis, bacteraemia and viraemia	30	1.24%
Carbohydrate tolerance analyses (incl diabetes)	28	1.16%
Vascular hypertensive disorders NEC	28	1.16%
Bullous conditions	28	1.16%
Inner ear signs and symptoms	27	1.12%
Hearing losses	27	1.12%
Pulmonary oedemas	27	1.12%
Bronchospasm and obstruction	26	1.07%
Neutropenias	26	1.07%
Total fluid volume decreased	26	1.07%
Abortions spontaneous	25	1.03%
Muscle pains	25	1.03%
Coughing and associated symptoms	25	1.03%
Peripheral neuropathies NEC	25	1.03%